

**REMARKS**

Claims 1-4 and 8-12 are pending. Claims 2-4 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Upon entry of these amendments, claims 1 and 8-12 will be pending. No new matter enters by way of these amendments.

**I. Specification – Title**

The Office again alleges that “the title is not descriptive of the elected subject matter,” and argues that a “new title is required that is clearly indicative of the invention to which the claims are directed.” Office Action at page 2. Applicants respectfully disagree, however, to facilitate prosecution, Applicants have amended the title to: “PLANT GENOME SEQUENCE.” Accordingly, based on the foregoing, Applicants respectfully request that the Examiner withdraw the objection to Applicants’ title.

**II. Rejection under 35 U.S.C. §101**

Claims 1-4 and 8-12 stand rejected under 35 U.S.C. § 101 “because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.” Office Action at page 3. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including “genomic mapping, gene identification and analysis, plant breeding, preparation of expression constructs, preparation of transgenic plants, screening for traits, and determination of polymorphisms and of associations between

polymorphisms and traits.” Office Action at page 4. The Examiner asserts, however, that the “claimed invention is not supported by a specific, substantial, and credible asserted utility because the disclosed uses are generally applicable to broad classes of this subject matter.” Office Action at page 3. In addition, the Examiner asserts that “[F]urther characterization of the claimed subject matter would be required to identify or reasonably confirm a ‘real world’ use.” *Id.* at pages 3-4.

The “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form.” *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use to identify a polymorphism in a population of plants. *See, e.g.* Specification at page 60, line 26 through page 68, line 2. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit.

The “threshold for utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

The courts have expressed a test for utility that hinges on whether an invention provides an “identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an “identifiable benefit” may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or “substantial” benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be “totally incapable of achieving a useful result,” *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use as nucleic acid molecule markers and probes (*see, e.g.*, specification at page 24, line 8 through page 30, line 5 and page 48, line 2 through page 60, line 25); to identify and obtain nucleic acid homologues (*see, e.g.*, specification at page 37, line 19 through page 38, line 20); in microarrays as gene-specific targets (*see, e.g.*, specification at page 68, line 3 through page 71, line 12); to identify the presence or absence of a polymorphism (*see, e.g.*, specification at page 60, line 26 through page 68, line 2); use to transform plants (*see, e.g.*, specification at page 73, line 7 through page 90, line 2); to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.*, specification at page 68, lines 3-23); and use to

overexpress or suppress a desired protein (*see, e.g.*, specification at page 90, line 3 through page 93, line 12).

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope, or the other laboratory equipment described by the Examiner, under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Applicants maintain that many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope described by the Examiner. Office Action at page 7. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by arguing that “uses that are generally applicable to any nucleic acid cannot be considered a specific and substantial use for a particular nucleic acid molecule.” Office Action at page 8. In short, the Examiner again suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”). Such an

argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d

1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner also asserts that the claimed nucleic acid molecules lack utility apparently because the specification has not identified "any particular polymorphisms associated with a trait or traits, identified any particular promoters or regulatory elements useful in methods of recombinant gene expression, determined that any of the putative open reading frames in the sequence actually encodes a protein having a specific use, etc." Office Action at page 5. Applicants respectfully submit that the skilled artisan would be able to ascertain these uses and activities based on Applicants' disclosure and tools available to practitioners in the art, *e.g.*, BLASTX. Furthermore, such disclosure is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications. The claimed sequence has utility even without such disclosure, *e.g.*, of a particular polymorphism associated with a trait or traits. The presence or absence of a polymorphism between two or more populations demonstrates

genetic heritage. For example, the absence of a polymorphism usually indicates that the two (or more) populations being compared share a common genetic heritage.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner “must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) (“Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under

Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

### **III. Rejection under 35 U.S.C. § 112, first paragraph, Enablement**

Claims 1-4 and 8-12 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 6. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

In addition, the Examiner appears to argue that claims 2-4 are not enabled because “it is not clear what is meant by the language ‘capable of specifically hybridizing;’ however, it is apparent that this language may encompass numerous molecules that hybridize under conditions of ‘moderate stringency.’” Office Action at page 10. Applicants respectfully disagree with the Examiner’s rejection of claims 2-4 and assert that the claims are enabled by the specification. However, to facilitate prosecution, claims 2-4 have been cancelled without prejudice to or disclaimer of the underlying subject matter.

The Examiner also alleges that claims 8-12 are written to “encompass molecules that are 90%-100% identical to SEQ ID NO: 7212 or its complement, and further embrace flanking sequences of unspecified length and identity.” Office Action at page 10. The Examiner alleges that “[t]he specification has not disclosed a specific and substantial utility even for, e.g., a particular nucleic acid consisting of SEQ ID NO: 7212,



and further does not teach a biological function for the large genus of molecules encompassed by the claims, or otherwise provided guidance with respect to how such molecules may be used in a utility meeting the requirements of 35 USC 101.” *Id.* Applicants again respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

#### **IV. Rejection under 35 U.S.C. § 112, first paragraph, Written Description**

Claims 1-4 and 8-12 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action at page 11. Claims 2-4 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond as the rejection applies to claims 1 and 8-12. Applicants respectfully traverse this rejection.

The Examiner, acknowledges that “[n]ucleic acids consisting of SEQ ID NO: 7212 meet the written description requirements.” Office Action at page 11. However, the Examiner argues that “the specification does not exemplify nucleic acids that ... have 90-99% identity with SEQ ID NO: 7212. *Id.* at page 12. The basis for the Examiner’s rejection is that the claims “encompass allelic and splice variants SEQ ID NO: 7212 and fragments thereof, naturally and non-naturally occurring mutants of these sequence, variants isolated from other organisms, etc.” *Id.* Apparently, the Examiner contends that “the specification does not exemplify any specific nucleic acids that ... have 90-99%

identity with SEQ ID NO: 7212.” *Id.* In addition, the Examiner suggests that the use of the open claim language “having” or “comprising” includes “molecules that are 90-100% identical with SEQ ID NO; 7212 and which further include undefined flanking sequences.” “ *Id.* Applicants respectfully disagree.

It is well-established law that use of the transitional term “comprising” or “having” leaves the claims “open for the inclusion of unspecified ingredients even in major amounts.” *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of “unspecified ingredients” is that they are not specified or described. The Examiner attempts to turn the legal meaning of “comprising” on its head. The claims recite the required nucleic acid sequences and recite percent sequence identities. Applicants’ amended claims do not recite proteins and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed

invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of nucleic acid molecules having SEQ ID NO: 7212, and sequences with the recited percent identity and therefore, the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.*, specification at page 25, line 14 through page 27, line 24; page 30, line 24 through page 42, line 6; and page 60, line 26 through page 68, line 2). The specification also describes appropriate hybridization conditions (*see, e.g.*, specification at 22, line 25 through page 23, line 11); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 38, line 5 through page 42, line 6); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 43, lines 8-19); nucleic acids comprising introns, intron/exon junctions, or both (*see, e.g.*, specification at page 42, lines 9-15); plant homologue proteins (*see, e.g.*, specification at page 43, line 20 through page 44, line 11); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.*, specification at page 71, line 19 through page 73, line 6); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.*, specification 73, line 7 through page 92, line 9). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the

Examiner maintains that “given the lack of any functional requirements in the claims, the single molecule exemplified in the specification (SEQ ID NO: 7212) is not representative of the broad genus of molecules embraced by the claims.” Office Action at page 13.

The Examiner argues that “while the instant claims recite structural properties of the molecules encompassed thereby, the claims fail to define the claimed molecules in terms of their functional properties.” *Id.* at page 12. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed a common structural feature, the nucleotide sequence of SEQ ID NO: 7212. Moreover, it distinguishes the members of the claimed genera from non-members.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 1 and 8-12 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

**V. Rejection under 35 U.S.C. §112, Second Paragraph**

Claims 2-4 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at page 13.

Claims 2-4 are allegedly indefinite in the recitation of the phrase “capable of specifically hybridizing to” because “[C]apability is a latent characteristic, and it is not clear whether the molecules of the claims do in fact ‘specifically hybridize’ or whether they are merely ‘capable of’ doing so under particular conditions, following modifications, etc.” Office Action at page 13-14. In addition, the Examiner alleges that “it is not clear from the teachings of the specification or the art as to what types of hybridization would be considered ‘specific’ within the context of the claimed invention.” *Id.* at page 14. Applicants respectfully disagree.

The skilled artisan would readily understand the phrase “capable of specifically hybridizing to” based on the specification. *See, e.g.*, specification at page 23, lines 8-11. However, in order to facilitate prosecution, claims 2-4 have been cancelled without prejudice to or disclaimer of the underlying subject matter. As such, Applicants respectfully request that the Examiner withdraw this indefiniteness rejection.

### Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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